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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,658	07/22/2002	Alvin Berger	112843-044	6858

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,658	BERGER ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1 and 3-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicant's remarks and amendments to the claims dated 7/24/06 is acknowledged.

Status of Claims

Claims 1, 3-25 are pending in the application.

Claim 2 was previously cancelled.

Status of Office Action: Final

Rejections:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. In view of the amendments to the claims, the rejection of claim 1 under U.S.C. 112, second paragraph is withdrawn.

2. Claims 15, 16 and 17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of claims 1, 2 and 5 under 35 U.S.C. 102(b) as being anticipated by Mechoulam et al (US 5, 618, 955) is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, and 3-25 as unpatentable under 35 U.S.C. 103(a) over Mechoulam et al (US 5, 618, 955) in view of the combination of Stordy et al (WO 96/37200, Makriyannis et al (US 5, 874, 459) and Kyle et al (WO 94/28913) is maintained.

Response to Arguments

1. Applicant's arguments filed 7/24/06 have been fully considered but they are not persuasive. Applicant argues that:

- In the Office Action, Claim 17 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Patent Office asserts that the specification does not enable one to practice the claimed methods of preventing the recited anandamide mediated ailment. Applicants respectfully disagree and submit that the specification along with the knowledge the skilled artisan would enable one to practice the claimed invention without undue experimentation.
- As set forth in the present specification, U.S. Patent No. 5,874,459 teaches that anandamide may act as a ligand, which interacts with cannabinoid receptors in the central nervous system and gut and/or immune cells and tissues. Beside this, numerous physiological effects (e.g. calming effects and effects on the immune system) of anandamide are mentioned in prior art literature as well as in the present application. See, specification, page 4, line 4 to page 5, line 20. For those skilled in the art, the physiological function of CB 1 and CB2 receptors, as well as functional disorders in which these receptors are involved are understood. On the basis of this general

knowledge of a skilled person and in combination with the information provided in the present specification, the knowledge concerning the treatment or prevention of a specific ailment may be readily transferred to other anandamide-mediated ailments such as those listed in Claim.

To respond to this argument, it is noted that, the recited composition may reduce the risk of the ailments recited in claim 17. It is not expected that all these diseases could be prevented since there are multiple factors and etiologies controlling each ailment in the recited list. The following are only some examples of these factors:

Hypertension has a genetic factor.

Pain depends on its etiology (such as menstrual pain)

Migraine headaches may result from an intracranial tumor, etc.

It is clear that the instant composition cannot act on all theses factors. Accordingly, the discussed health problems cannot be prevented.

- Applicants respectfully submit that compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed. See, MPEP 2164.02. An example may be "working" or "prophetic." A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. In fact, the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Although studies have not been conducted in the individual cases for every

listed ailment, these studies are within the capabilities of the skilled artisan and do not require undue experimentation. Moreover, it is understood by the skilled artisan that compounds used for treating an ailment can also be used for preventing that ailment.

To respond to the previous arguments, please see M.P.E.P. 2164.02 which states that: The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art.

Since applicant cannot show that the current composition is capable of preventing the recited ailments the skilled artisan will have a great burden of undue experimentation, this renders the working examples an essential factor to avoid the unpredictability of the subject matter.

- Regarding Claims 15-17, the Patent Office asserts that the health problems are not specified. In response, Applicants have amended Claims 15-17 to remove some of the ailments. Applicants respectfully submit that each of the listed ailments are understood by the skilled artisan. For example, the scope of the terms "gut upset" as well as "intestinal motility disturbances" (not "intestinal motility") are commonly understood by the skilled artisan (e.g. Ph.D. in clinical nutrition). The term "vocalization" is defined in the specification, for example, at page 6, lines 13-18. Moreover, the remaining ailments are readily known and understood by the skilled artisan. As a result,

the skilled artisan would understand the metes and bounds of Claims 15-17 in view of the specification and their own knowledge.

To respond to these arguments, it is noted that most of the recited ailments in claims 15-17 are not expressing specific diseases, however, they are representing symptoms or signs of multiple diseases (e.g. pain, insomnia, inflammation, etc.). Because these symptoms or signs have different etiologies, it is considered indefinite, the skilled artisan would not be able to determine metes and bounds of claims 15-17. Examiner included in the rejection of record that Applicant is required to determine the exact disorders included that can be treated by using the nutritional preparations recited in the claims (page 7).

Definitions of **ailment** on the Web:

An illness that is not serious
www.kented.org.uk/ngfl/subjects/history/medhist/page45_glossary.html

any bodily or mental disorder
healthandfitness.com/glossary.html

- Mechoulam is directed to polyunsaturated fatty acid amides and their derivatives, which are themselves final synthesis or end products. See, Mechoulam, column 1, lines 10-16. As a result, they are not further metabolized to a compound having anandamide activity as required, in part, by Claim 1. In fact, Mechoulam fails to disclose or suggest anywhere metabolizing a precursor to a compound having anandamide activity. The Mechoulam compounds exhibit physiological activity and are useful as active ingredients in pharmaceutical compositions for the treatment of several diseases. Nevertheless, Mechoulam is entirely directed to the use of final synthesis or end products, namely, the polyunsaturated fatty acid amides and their derivatives and not

any to any compounds utilizing the intermediates or precursors for forming these polyunsaturated fatty acid amides.

In response to this argument, it is clear that Mechoulam used the same compounds. If applicant reviews claims 1, and 9 of Mechoulam and assume that m=2, it is noted that the compounds used in Mechoulam's and the instant compositions are the same. Note that Mechoulam claims that m=small integer and that the number 2 of methyl groups suggested in instant claim 1 is inherently a small integer. The Examiner would like also to explain that Mechoulam discloses the same formula of anandamide, and since the instant claimed invention is a composition, the mechanism of action of the claimed composition is inherent. In addition, the mechanism should not be given a patentable weight; because the prior art's similar compositions would be at least capable inherently of achieving the same mechanism. Accordingly, regardless of which mechanism Mechoulam's composition was claimed to go through the mechanism targeted by the instant application should be achieved.

- As discussed previously, Claim 1 is directed to compositions utilizing a precursor (e.g. intermediate) that is metabolized to form a compound having anandamide activity. For example, the precursor can be metabolized endogenously or within the human body to form a compound having anandamide activity. In contrast, Mechoulam discloses compounds that exhibit anandamide activity that are already in their final form prior to entering the body and not further metabolized in the body. Consequently, Mechoulam fails to disclose or suggest precursors that are

metabolized to a compound having anandamide activity and used as active compounds in a nutritional composition as required, in part, by Claim 1.

To respond to this argument, it is not essential that the reference suggests or mentions literally the word "metabolized". A compound and its properties are not separable, the prior art clearly administers same ingredient for the same disorders. It is not necessarily that the prior art recites literally each and every mechanism that a compound can go through.

Affidavit under 37 CFR 1.132

The affidavit under 37 CFR 1.132 filed 10/17/05 is insufficient to overcome the rejections of claims 1, 5, 16, 22, and 26 based upon 35 USC § 112, 35 USC § 102, and 35 USC § 103 as set forth in the last Office action because:

- The enablement rejection of claim 17 is not affected by the affidavit since applicant fails to demonstrate an enablement of instant invention to prevent the ailments recited in claim 17.
- The 35 USC § 102 (b) of record cannot be overcome by the affidavit of record.
- The 35 USC § 103 is not overcome since applicant did not show side-by-side comparison or showing of unexpected results of the instant application. The affidavit is mainly another argument of the rejection of record.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim, M.D. **9/28/06**

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER